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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,421	01/06/2005	Werner Simon	12874-00003-US	9776

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EXAMINER	
AULAKH, CHARANJIT	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,421	SIMON ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. According to a preliminary amendment filed on Jan. 6, 2005, the applicants have amended claims 3-6 and 8-11 and furthermore, have added new claims 12-15.

2. Claims 1-15 are now pending in the application.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In independent claim 1 as well as claims 4, 5 and 13-15, the applicants mention the term ----inclusion compounds-----. However, there is no written description regarding these inclusion compounds in the specification.

In claim 7, the applicants mention the term --- combination with further agents for tumor treatment----. However, there is no written description regarding these agents in the specification.

6. Claims 3 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of prior art, unpredictability and the breadth of claims.

In regard to claim 3, the claims are directed to compounds where variable R2 has higher water solubility as compared to compounds where R2 is CH=CH-CH=CH-CH3. However, there is no teaching in the specification regarding this higher water solubility of all values of variable R2 as compared to CH=CH-CH=CH-CH3. There are no working examples present showing higher water solubility of a single value of variable R2 as compared to CH=CH-CH=CH-CH3.There is no teaching either in the specification or prior art references provided to show variables such as alkyl groups, amino groups, aryl groups, cycloalkyl groups or heteroaryl groups to have higher water solubility as

compared to CH=CH-CH=CH-CH3 groups. There is lot of unpredictability. The instant compounds of formulae Ia and Ib encompass several hundreds of thousands of compounds based on the values of variables R1-R8, Y1-Y3 and X1-X2 and therefore, in absence of such teachings, presence of working examples, the state of the prior art and unpredictability, it would require undue experimentation to select compounds with different values of variable R2 having higher water solubility as compared to compounds having R2 as CH=CH-CH=CH-CH3.

7. In regard to methods of treatment of instant claims 7-12, the specification is enabling only for treating lung tumors, renal tumors, prostate tumors, uterus tumors and melanoma since exemplified compound 3 was shown to be effective in these tumor cell lines as shown in table 7 on page 19. However, there is no teaching in the specification regarding inhibition of topoisomerases I and II by the instant compounds. There is no guidance or direction present for assessing such inhibition by the instant compounds. There is no teaching, guidance or direction present to show how the instant compounds will have utility in treating every known tumor, every parasite, immunosuppression or neurodermitis. There are no working examples present showing efficacy of instant compounds in known in vitro or in vivo models of every tumor, parasitic infections, immunosuppression or neurodermitis. The instant compounds are novel and differ from the prior art compounds by having substituent –X2-R6 and therefore, there is lot of unpredictability regarding efficacy of instant compounds in treating every tumor, parasitic infections etc. The instant compounds of formulae Ia and Ib encompass several hundreds of thousands of compounds based on the values of variables R1-R8,

Y1-Y3 and X1-X2 and therefore, in absence of such teachings, guidance, presence of working examples, the state of the prior art and unpredictability, it would require undue experimentation to demonstrate the efficacy of instant compounds in known in vitro or in vivo models of every known tumor, parasitic infections, immunosuppression or neurodermitis and hence their utility for treating these disorders.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1 as well as claims 4 and 13-15, the values of variable R2, R5 and R6 defined as ---CmH2m+o-pYp---- are confusing and indefinite since their meaning is not clear. The actual intent is not clear. The applicants should clearly define these values.

In claims 1, 3, 4 and 12-15, the applicants use the term ---means--- for defining various variables. The applicants are suggested to use the term ----represents---- or simply – is---. Also, the applicants are suggested to insert ; (semicolon) after defining each variable instead of , (coma).

In claim 1, 4, 5 and 13-15, the term ---inclusion compounds --- is indefinite since these compounds are not defined in claims or in the specification.

In claims 1, 3 and 12, the term --- residue --- is vague. The applicants are

suggested to use the term ---variables---.

In claims 4 and 13-15, the applicants mention the term ---particularly --- for some values for variable R2. Are these preffered embodiment? The actual intent is not clear.

In claims 6-11, the terms --- drugs or preparation of drugs ------ are vague and indefinite since actual intent is not clear. Are there other active pharmaceutical compounds present in these drugs besides instant compounds of formulae Ia and Ib ? The applicants are suggested to use the term ----pharmaceutical composition ----.

In claim 7, the term ---- further agents ---- is indefinite since these agents are not defined.

Claim 3 recites the limitation "residues R" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "residues R" in claim 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 9-11 provide for the use of compounds according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Allowable Subject Matter

12. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Latham (Cancer Cheother. Pharmacol., cited on applicants form 1449) discloses fredericamycin A (see page 168) which is closely related in structure to the instant compounds of formula Ia. However, this compound differs from the instant compounds in lacking instant variable X2-R6 and furthermore, there is no teaching, suggestion or motivation in the prior art to modify the compounds of Latham to prepare the instant compounds.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

C. S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625